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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/917,384	07/28/2001	William S. Adney	NREL 01-38	9964

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EXAMINER

CHOWDHURY, IQBAL HOSSAIN

ART UNIT	PAPER NUMBER
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1652

MAIL DATE	DELIVERY MODE
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09/20/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/917,384

Applicant(s)

ADNEY ET AL.

Examiner

Iqbal H. Chowdhury, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 19-21, 23-25, 31-34, 69-74, 78-80 and 85-90 is/are pending in the application.
- 4a) Of the above claim(s) 85-88 and 90 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 19-21, 23-25, 31-34, 69-74, 78-80, 89 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Application Status

In response to a previous Office action, a Final requirement (mailed on August 4/30/2007), Applicants filed an amendment on July 2, 2007, adding new claims 85-90 is acknowledged. Claims 12-18, 22, 26-30, 35-68, 75-77, and 81-84 remain cancelled.

Claims 1-11, 19-21, 23-25, 31-34, 69-74, 78-80, 85-90 are currently pending in the instant application.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 07/02/2007 has been entered.

New claim 89 recites the subject matter of this group and under consideration for examination. However, new claims 85-88 and 90 recite the subject matter of Group IV of the restriction requirement set forth on 7/3/2002 and thus are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as reciting a nonelected invention.

Therefore, claims 1-11, 19-21, 23-25, 31-34, 69-74, 78-80 and 89 are under consideration and will be examined.

Applicants' arguments filed on July 2, 2007, have been fully considered but are not deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

New-Claim Rejections - 35 U.S.C. § 112(2)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 1-11, 19-21, 23-25, 31-34, 69-74 and 78-80 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite and vague for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1, 6, 79 and 80 are indefinite in the recitation “at least about 95 or 98%”, which is ambiguous and confusing. It is unclear whether applicant meant “at least 95 or 98%” or “about 95 or 98%”. However, “about 95 or 98%” is unclear and vague, as it is not clearly stated in the specification about what is the scope of “about 95 or 98%” mean? In addition, the combination of “at least about 95 or 98%” is ambiguous and confusing.

Claim 89 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 89 recites “hybridizes with a complement” which is unclear as to whether it is limited to the full-length complement or includes partial complements or fragments thereof. For purpose of the further examination, it is presumed that applicants intended to hybridize with the full-length complement.

Claim 89 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite and vague for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In the present instance, claim 89 recites the phrase “hybridizes with a complement ---- SEQ ID NO: 2 in a high stringency hybridization reaction at 42oC for 2.5 hours in 6XSSC/0.1% SDS”, which is not considered as high stringency hybridization condition. At

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this high salt and low temperature constitutes a low stringency hybridization condition, which would allow many unrelated nucleic acid sequence to hybridize. Besides, there are no washing steps, which would be correlated with the desired hybridization condition to remove non-specific nucleic acid molecules. Therefore, it is not clear to the Examiner how this condition constitutes a high stringent condition without any washing step.

New-Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 89 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polypeptide of SEQ ID NO: 1 having exoglucanase activity isolated from *Acidothermus celluliticus*, does not reasonably provide enablement for any exoglucanase encoded by a DNA having the ability to hybridize with the complement of the DNA of SEQ ID NO: 2 under recited hybridization conditions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, **to make and use** the invention commensurate in scope with these claims.

Claim 89 is so broad as to encompass an exoglucanase protein encoded by any DNA having the ability to hybridize with the complement of the DNA of SEQ ID NO: 2 under recited stringent hybridization conditions.

The specification defines the conditions to be considered as high stringency, is in fact a low stringency condition (see 112, 2nd rejection). Therefore, the nucleic acids having 50-80%

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identical to SEQ ID NO: 2 would hybridize at the recited condition. The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of exoglucanases broadly encompassed by the claims. Since the low stringent conditions allow hybridizing with sequences having significant divergence from the nucleic acid sequence of the target sequence in the claims, which encompass a large number of nucleic acids and the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to the amino acid sequence of only one protein i.e. SEQ ID NO: 1.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple point mutations or substitutions.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including an exoglucanase encoded by a DNA having the ability to

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hybridize with the complement of the DNA of SEQ ID NO: 2 under recited stringent hybridization conditions. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of an exoglucanase encoded by a DNA molecule having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Maintained-Claim Rejections - 35 USC § 112(New Matter)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Previous rejection of Claims 1-11, 19-21, 23-25, 31-34, 69-74 and 78-80 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention as new matter is maintained. This rejection has been discussed at length in the previous office action and it is maintained for the reasons of record and discussed below.

Claims 1, 6, 19-21, 79-80 are drawn to polypeptide sequences that are "about 95%" or "about 98%" identical to SEQ ID NO: 1, 2, 4, 5, 6, and 7. However, the specification indicates that applicants have no support for the newly added language, which now constitutes a "new matter". Therefore claims 1, 6, 19-21, 79-80 and claims 2-5, 23-25, 31-34, 69-74 depending therefrom are rejected for introducing "new matter" into the claims. A perusal of the

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specification indicated support for only "90% identity" language and that too for only SEQ ID NO: 1 (page 18 of the specification).

In response to the previous Office action applicants argue by reciting some case law such as "The defendants in *Union Oil Co. v. Atlantic Richfield Co.* (1998 U.S. Dist. LEXIS 22847, 13-14 (D. Cal. 1998)) argued that none of the combinations of property ranges in the claims appeared in the specification as it was originally filed, and thus, the claims lacked written description support. However, the District Court in denying the defendant's requested JMOL pointed out that "whether a patent is invalid for lack of a written description turns not on whether the specifications as filed set forth each and every facet or descriptor of the invention, but whether the written description is sufficient to be satisfied that the claimed inventor did in fact invent the patented work." When the case was appealed, the Federal Circuit quoting *In re Gosteli* (872 F.2d 1008, 1012, 10 U.S.P.Q.2D (BNA) 1614, 1618 (Fed. Cir. 1989)) asserted that the written description requirement does not require the applicant "to describe exactly the subject matter claimed, [instead] the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." *Union Oil Co. v. Atlantic Richfield Co.*, 208 F.3d 989,997 (Fed. Cir. 2000)" and applicants further argue that it is apparent from these cases that "an explicit recitation" is not necessary to find claims supported by Applicants' specification". The Examiner acknowledges the citation of *Union Oil Co.* that implicit support is acceptable but the specification nowhere provides such implicit support for 95% identity to SEQ ID NOs: 4-7. Besides, the fact pattern of the application of *Union Oil Co.* is completely different than the instant claims. In some cases implicit statement may be sufficient to satisfy Written description requirement and provide evidence that applicants had possession of the claimed

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invention. In the instant case, applicants do not have any support for polypeptides having at least 95% sequence identity to SEQ ID NO: 4, 5 and 7 (claims 1, 6, 19-21), or 95% or 98% sequence identity to SEQ ID NO: 1 (Claims 79 and 80), which encompass many mutants and variants within this range of sequence identity. Applicants only have support for a polypeptide having 90% sequence identity to SEQ ID NO: 1. Applicants are reminded that here the issue is not lack of scope of enablement but “new matter” i.e. applicants can claim what is described at the time of the filing.

Applicants also argue that they have described various ways in which the sequence identity can be altered, including additions to or subtractions from the reference sequence, as well as substitutions, fusions, truncation and further stating that Applicants had possession of polypeptides with 95% and 98% sequence identity to any one of SEQ ID NOs 4, 5, and 7. This is not found persuasive because it would not change the core issue of “new matter” and substitution or truncation is not same of a polypeptide having 95 or 98% identity to SEQ ID NO: 1, 4, 5 and 7. Furthermore, Applicants argue that the specification recite “substantial”, or “at least about 90%”, which covers the scope of any polypeptides sequences having 91%, 92% --- 99% identity to SEQ ID NO: 1, 4, 5 and 7. This is not found persuasive because “substantial” indefinite term as well as “at least about” (see new rejection, 112, 2nd). Regarding to the arguments of “substantial” and “at least about 90%” encompassing the scope of 91%, 92%, --- 99%, while a skilled artisan would understand that this recitation encompassed all of these, but it does not either explicitly or implicitly provide an understanding that applicants intended the scope of the invention to be limited to only 95% (or 98%) identity to these SEQ ID NOs. Again, the core issue is “new matter”, which cannot be cured by adding the phrase “substantial” or “at least

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about". The question here is what the applicants chose to claim at the time this application was filed. Without an explicit or implicit recitation of all the per cent homologies or per cent identities of sequences as support for the claim amendments that were contemplated at the time this application was filed, reciting them at this stage in the prosecution of the application raises the issue of "new matter". Therefore, the rejection is maintained.

Conclusion

Claims 1-11, 19-21, 23-25, 31-34, 69-74, 78-80 and 89 are rejected.

Claims 7-11, and 78 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Iqbal Chowdhury, Ph.D. whose telephone number is 571-272-8137. The examiner can normally be reached on 9:00-5:00.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on 703-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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